UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	Judge Patti B. Saris
	Chief Mag. Judge Marianne B. Bowler

PLAINTIFFS' OPPOSITION TO MOTION FOR PROTECTIVE ORDER

Simply put, defendants' motion for a protective order is frivolous. Defendants assert two grounds for their motion: (1) "the discovery plaintiffs seek is wholly irrelevant to this action," and (2) such discovery would be an "unwarranted burden." Track 1 Defendants' Mem. at 1.

Given the liberal reach of Federal Rule of Civil Procedure 26(b)(3), neither argument has an ounce of merit. As to relevance, the average sales price ("ASP") is a calculation that includes all of the discounts, rebates, chargebacks, and other special deals not included in the reported average wholesale price ("AWP"). Ultimately at the trial of this case, plaintiffs will use the spread between ASP and AWP as a benchmark to prove (1) that the published AWPs are phony and highly inflated, and (2) as a possible measure of damage to plaintiffs and the class. Thus, defendants' calculation as to the ASP for each drug is not only relevant – it is critically relevant.

As for the "unwarranted burden," defendants have already produced the information to the Centers for Medicare and Medicaid Services ("CMS"). Thus, having a witness explain information that is highly technical, but which has already been gathered and produced to CMS, is hardly a burden.

On the other hand, denial of the discovery would prejudice plaintiffs. This information will assist plaintiffs in showing the uniformity of defendants' price inflation scheme. As it now stands, with plaintiffs' class certification motion due in less than 90 days, the Track 1 defendants either have not all produced data from which ASPs can be calculated, or have produced raw data from which ASPs might be abstracted, but it is an exceedingly difficult task, and one that is time consuming. Access to an already calculated ASP for each drug will greatly assist plaintiffs and their experts and will act as a factual support for plaintiffs' case.

I. BACKGROUND

A. The AWP Inflation Scheme

At issue in this motion is the relevance of discovery directed at defendants' recently compiled and reported ASPs.[1] To understand why plaintiffs seek such data, a brief explanation of AWP is required.

The complaint alleges that for the last decade, the Defendant Drug Manufacturers have conspired with others in the pharmaceutical distribution chain, including but not limited to physicians and hospitals (hereafter "medical providers" or "providers"), pharmacy benefit managers ("PBMs") and various publishing entities, to collect inflated prescription drug payments from plaintiffs and the Class.[2]

More specifically, the Defendant Drug Manufacturers report to trade publications a drug price – the Average Wholesale Price (or "AWP") – that for many drugs is deliberately set far above the prices that these drugs are available in the marketplace. The AWPs for these drugs are deliberately false and fictitious and created solely to cause plaintiffs and the Class members to overpay for drugs. Because all drugs administered under Medicare Part B are priced based on

[1] Defendants themselves have served over 100 third party subpoenas and have issued dozens of deposition notices. One wonders why, given the enormity of discovery, they object to one deposition for each company. A reasonable inference is that defendants fear that revelation of the ASPs will demonstrate the disparity between ASP and AWP.

[2] Amended Master Consolidated Class Action Complaint Modified Per the Court's Instruction at the November 21, 2003 hearing ("AMCC") at ¶ 2.

the published AWPs, the Defendant Drug Manufacturers inflate AWP reimbursement rates to enable providers and others to make secret profits through overcharges to patients, their insurers and other end payors. This, in turn, motivates the providers to sell and administer the drugs with the most inflated AWPs, resulting in increased market share and profit for the Defendant Drug Manufacturers and inflated payments for drugs by individual patients (through co-pays or direct payments), health plans and insurers.

For drugs reimbursed by Medicare Part B (which generally, but not always, require administration in a provider's office), the health care providers administer the drugs and are reimbursed by Medicare based on the inflated AWP. Thus, the providers benefit by pocketing the "spread" between the AWP and the actual cost that they pay for the drugs, and the Defendant Drug Manufacturers benefit by increasing the sales of their drugs that are covered by Medicare Part B ("Covered Drugs") and by increasing their market share. In some cases, the Defendant Drug Manufacturers also provide chargebacks, rebates, hidden price discounts and/or other unlawful financial inducements, including free samples, to further increase the provider's spread and, therefore, their incentive to prescribe a particular Defendant Drug Manufacturer's product. Those discounts are not used by the Defendant Drug Manufacturers in calculating the published AWPs, resulting in their inflation. AMCC ¶ 4.

The use of AWP is not limited to Medicare reimbursement. Rather, AWP is a benchmark from which hundreds of drug prices are derived in transactions throughout the pharmaceutical distribution chain. For "Part B covered drugs" administered outside of the Medicare Part B context, non-Medicare patients and health plans pay for these drugs based on the inflated AWP with an intermediary (for example, a pharmacy benefit manager) pocketing the "spread" between the AWP and the actual cost that the intermediaries pay for these drugs. And similar to the benefit that the Defendant Drug Manufacturers obtain through the AWP scheme for Part B drugs, the Defendant Drug Manufacturers also benefit from the AWP scheme with respect to these drugs by increasing the sales of their particular AWP-inflated drugs and their market share

for those drugs. The use of AWP as a benchmark for reimbursement is also not limited to Part B drugs being administered outside of Medicare, but extends to thousands of other drugs as well. And again, with respect to these non-Part B drugs, it is the end payor, be it a health plan or private insurer, that pays the inflated amount. All others in the distribution chain, be they wholesalers, pharmacies or pharmacy benefit manufacturers, benefit from the spread between AWP and actual costs. AMCC ¶ 5.

Thus, in a perversion of the type of competitive behavior expected in a market not subject to illegal manipulation, the Defendant Drug Manufacturers often promote their drugs not based on lower prices, but by the use of reimbursement rates based on a fictitious and inflated AWP that allows purchasers and intermediaries (including providers and PBMs) to make inflated profits – and the Defendant Drug Manufacturers to increase their market share – at the expense of plaintiffs and the Class. AMCC ¶ 6.

The Defendant Drug Manufacturers also caution providers and other intermediaries that the success of the high profit scheme will be jeopardized if anyone discloses the significantly lower prices actually paid for the drugs (allowing the scheme to be concealed and to continue). All Defendants actively conceal, and caused others to conceal, information about the true pricing structure for the prescription drugs, including the fact that the AWPs for the drugs are deliberately overstated. And, all those in the distribution chain also conceal the rebates, free samples, educational grants and other economic rewards which they receive, but which are not reflected in calculating AWP. AMCC ¶ 7.

The importance of an accurate AWP was recently reconfirmed by the Office of the Inspector General ("OIG") in an April 2003 report: "Compliance Program Guidance for Pharmaceutical Manufacturers." The OIG report found that the "government sets reimbursement with the expectation that the data provided are complete and accurate." The OIG report made it clear that the AWP must be a meaningful figure that is not artificially inflated:

> ***Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers***. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues). Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements. (Emphasis added.) (AMCC ¶ 153.)

The AMCC alleges that each of the defendants reported inflated AWPs and engaged in practices designed to increase the spread. A few examples from the AMCC illustrate the scheme as implemented by each of the Track 1 defendants.

In one internal marketing memorandum, AstraZeneca recognized the profits to providers from the inflation of AWPs: "The market we are in wants a more expensive Zoladex, because the doctor can make more money." (AZ0021838) (Highly Confidential) (AMCC ¶ 236(a)).

Similarly, in its agreements with PBMs, AstraZeneca guaranteed that it would maintain a spread between AWP and AWC (average wholesale cost) in order to ensure a profit to PBMs at the expense of the Class. (AZ0036207) (Highly Confidential). For example, in its agreement with Caremark, AstraZeneca stated:

> ZENECA WILL REIMBURSE CAREMARK FOR THE DIFFERENCE BETWEEN THE AMOUNT COLLECTED BY CAREMARK ON EACH PATIENT UNIT SOLD AND AWP AT THE TIME THE UNIT WAS DISPENSED. CAREMARK WILL HAVE EXERCISED BEST EFFORTS TO COLLECT THE FULL AWP FROM THE 3RD PARTY PAYER AND THE PATIENT PRIOR TO SUBMISSION TO ZENECA.

(AZ0036208) (Highly Confidential) (AMCC ¶ 236(b)).

AstraZeneca recognized that its practices were at the expense of the Class:

> BECAUSE OF OUR STEEP DISCOUNTING, NEARLY HALF THE PROFIT TO BE REALIZED WITH ZOLADEX IS PAID BY MEDICARE. AND SINCE MEDICARE IS THE QUICKEST AND MOST DEPENDABLE PAYOR, THIS WAS SEEN AS AN

> ENORMOUS BENEFIT. THE OTHER HALF OF THE PROFIT WAS FROM THE PATIENT CO PAY OR SECONDARY INSURANCE . . . .

(AZ0037011) (Highly Confidential) (AMCC ¶ 236(c)).

BMS also engaged in publishing inflated AWPs. In a report published by the DHHS, the DOJ documented numerous instances where the published AWPs for various dosages of five (5) drugs manufactured by the BMS Group were substantially higher than the actual prices listed by wholesalers. The chart below sets forth the BMS Group drugs identified by the DOJ and the spread associated with one particular dosage of each drug. These figures compare the DOJ's determination of an accurate AWP[3] for that particular dosage, based upon wholesalers' price lists, with the AWP reported by the BMS Group in the 2001 *Red Book*.[4]

Drug	**Manufacturer**	**BMS's 2001 *Red Book* AWP**	**DOJ Determined Actual AWP**	**Difference**	**Percentage Spread**
Amikacin Sulfate	Apothecon	$32.89	$17.31	$15.58	90%
Amphotercin B	Apothecon	$17.84	$6.20	$11.64	188%
Bleomycin Sulfate	BMS	$609.20	$509.29	$99.91	20%
Cyclophospamide	BMS	$102.89	$45.83	$57.06	125%
Etoposide (Vepesid)	BMS	$136.49	$34.30	$102.19	298%

GSK also engaged in marketing the spread. In marketing the new Zofran® premixed IV bag, GSK produced and used a document entitled "Profit Maximization – It's In the Bag." This document compared Kytril® to Zofran® based upon its total return of investment (ROI). Specifically, Glaxo's marketing materials including the following chart:

	Cost	AWP	Potential Reimbursement/ Patient	Reimbursement/ Year	ROI
Zofran 32mg bag	$110.41	$195.00	84.59	$13,957,350	76.6%
Kytril 1 mg vial	$102.73	$175.00	72.27	$11,924,000	70.3%

(P007114) (Highly Confidential) (AMCC ¶ 398).

[3] In effect, the DOJ was trying to determine ASP.

[4] AMCC ¶ 336.

In response to government subpoenas, the Schering Plough Group produced numerous price lists setting forth spreads between AWPs and prices apparently offered to wholesalers, providers and other intermediaries. A review of those price lists reveals that the Schering Group has consistently offered hundreds of its drugs and other solutions to its customers at prices significantly below the published AWP and that the spread was of great importance to its customers. To repeat every one of those drugs and the spread offered to each specific customer here is not practical. However, set forth below in Tables 1, 2 and 3 are a number of those drugs with spreads between the AWPs and direct prices. Table 1 is an analysis of certain dosages of Warrick drugs from a document entitled, "Amerisource" (WAR0022160) (Highly Confidential) (AMCC ¶ 486).

TABLE 1

LABEL (MFG)	GENERIC NAME	AWP	INVOICE COST	DIFFERENCE	PERCENTAGE SPREAD
Warrick	Albuterol Inhaler	21.41	5.75	15.66	272%
	Aug Beta Dip Oint 0.05%	43.20	26.90	16.30	61%
	Griseofulvin	82.47	37.22	45.25	122%
	Theophylline	11.70	2.83	8.87	313%

Table 2 is an analysis of certain dosages of Warrick drugs from a document entitled, "1997 Care Group Bid Proposal." (WAR0022122) (Highly Confidential).

TABLE 2

PRODUCT	**AWP**	**INVOICE PRICE**	**NET PRICE (AFTER REBATE)**	**DIFFERENCE BETWEEN AWP AND INVOICE PRICE**	**PERCENTAGE SPREAD**
Clotrimazole	22.25	7.77	6.99	14.48	186%
Perphenazine	78.00	19.53	17.58	58.47	299%

Table 3 is an analysis of certain dosages of Warrick drugs from a document entitled, "Managed Care Pricing," dated July 1, 2002. (WAR0054226) (Highly Confidential).

TABLE 3

Product	Minimum PBM/Mail Order/ Staff Price Guide	Target PBM/Mail Order/ Staff Price Guide	Minimum GPO Price Guide	Target GPO Price Guide	AWP	Difference	% Spread
ISMN	4.48	4.93	5.15	5.38	117.40	112.02	2,082%
Oxaprozin	11.42	12.56	13.13	13.70	117.40	103.70	757%
Potassium Chloride	9.67	10.64	11.12	11.60	65.00	53.40	460%
Sodium Chloride	6.12	6.73	7.04	7.34	24.30	16.96	231%
Sulcrafate Tablets	45.15	49.67	51.92	54.18	353.71	299.53	553%

B. ASP

The Office of the Inspector General ("OIG") has opined that AWP should take into account discounts, free goods, chargebacks and other rebates. AMCC ¶ 153. When Congress amended the Medicare law, it required manufacturers to report ASP, and to include discounts, free goods, chargebacks and rebates in calculating ASP. *See* 42 C.F.R. 414.804.[5] In other words, ASP includes the items omitted from published AWPs. This is intended to allow the government to receive a report of the "actual wholesale prices available to physicians, suppliers and large government purchasers," as opposed to the inflated AWPs.

The defendants each recently reported ASPs to CMS as required by law. They have already gathered and compiled the data that is the subject matter of plaintiffs' Rule 30(b)(6) notice. There is no question such compilation is complex and required an analysis of tens of thousands of transactions for each drug. However it has been done by the defendants.

C. Defendants Have Steadfastly Delayed Discovery and Continue to Do So While the Class Certification Motion Date Approaches

The history of defendants dodging discovery is lengthy. Plaintiffs need not repeat that history here because Judge Saris addressed such tactics in Case Management Order No. 10 ("CMO 10"). At plaintiffs' urging, Judge Saris required responses to document requests within 60 days of service. CMO 10 at Section II.4. For the most part, this rule has not been complied

[5] A copy is attached as Exhibit A.

with. Based on assurances from defendants that progress would be made in producing documents in a timely fashion, plaintiffs agreed to provide defendants some relief from these dates. Unfortunately, the transactional data needed to calculate ASPs has not been produced in many cases, is incomplete in others, or is not easily worked with. To address defendants' repeated refusal to produce 30(b)(6) witnesses, she ordered that they must be produced within 45 days of a request. CMO 10, Section II.6. Judge Saris also set September 3, 2004 for plaintiffs to file a class certification motion. Most of the Track 1 defendants will still be producing relevant material up to July 31, 2004, giving plaintiffs little time to sort through the documents, let alone use them in depositions. In this context, due to the importance of ASPs, and given the fact defendants have calculated them, plaintiffs sought a 30(b)(6) witness on this subject.

II. ARGUMENT

A. The Scope of Discovery Is Broad

Not cited by the Track 1 defendants in their motion is the standard governing this motion. The scope of discovery under Fed. R. Civ. P. 26(b)(1) is "very broad." *Cabana v. Forcier*, 200 F.R.D. 9, 17 (D. Mass. 2001). Under the liberal standard set forth in Rule 26(b)(1), "[I]nformation is discoverable if there is any possibility it might be relevant to the subject matter of the motion." *Id.* at 17, citing *EEOC v. Electro-Term, Inc.*, 167 F.R.D. 344, 346 (D. Mass. 1996). *See also Schuurman v. The Town of North Reading*, 139 F.R.D. 276 (D. Mass. 1991) (Bowler J.); *Sacramona v. Bridgestone/Firestone, Inc.,* 152 F.R.D. 428 (D. Mass. 1993) (Bowler J.); *Gagne v. Reddy*, 104 F.R.D. 454, 456 (D. Mass. 1984).

B. The Information Is Relevant

The ASPs (and information about the processes by which defendants compile them) directly impact issues that go to the core of the class certification and liability issues in this case. The following are only several examples.

First, the ASPs are living proof that the defendants can do that which they earlier said was impossible – calculate in an administratively efficient manner a reasonable standard upon

which reimbursement might be based. When the AWP cases were first filed in 2001, Medicare Part B reimbursement remained entrenched in the AWP-based system, a system abused terribly by the defendants. Part of the defendants' response to these lawsuits – lawsuits that sought, and still seek, changes in corporate behavior – was that it was unrealistic, impractical or anticompetitive to demand that defendants calculate ASPs and make them available to others.

Congress now requires ASPs (at least for Medicare Part B reimbursement). The system has been changed (in no small part as a result of the defendants gaming the old one). The defendants still wish to have the federal government spend about $10 billion per year for Medicare Part B drugs. Lo and behold, the defendants can now produce ASPs to the government – it isn't unrealistic, impractical or anticompetitive to do so.

Second, the ASPs serve as a basis for showing a methodology by which to calculate actual transaction prices for Medicare Part B drugs, an issue directly implicated in class certification. Both for current damages impact and for showing a method by which damages might be calculated for earlier periods (by using the current methodology for calculating ASP and applying it to earlier time periods), the ASPs demonstrate class certification ease and damages approaches.

Third, this case seeks corporate change. The ASPs currently being calculated by the defendants and produced to CMS will hopefully add some honesty into the price reporting conduct of the defendants *as it relates to Medicare Part B reimbursement*.[6] However, and as the AMCC alleges, defendants' fraudulent drug reimbursement practices exist in the mail order and pharmacy distribution channels as well, and involve many more drugs than just those that are covered by Medicare Part B. Disclosure of the Medicare Part B ASPs, and information about the methodology of their calculation, dissemination and use, will be directly relevant to the

[6] We acknowledge, therefore, that to some extent in the area of Part B reimbursement, the corporate change originally sought by the lawsuit has, in effect, been achieved by Congress' enactment of the Medicare Modernization Act. Congress chose to change the system rather than require honesty within the AWP-based one, but the effect (hopefully) will still be to require, as to some drugs, that real reimbursement prices be disclosed.

plausibility of change outside of Medicare as well as to calculation of damages and showing class wide injury.

Given the broad discovery standard, there is little question of the relevancy of the ASPs for each drug. This information is in effect a proxy for what the AWP would have been but for the scheme to report inflated AWPs. The fact that it is current does not diminish its relevancy as plaintiffs allege a continuing wrong and course of conduct. Further, the fact that it is current does not diminish the fact that it will provide a benchmark from which plaintiffs and their experts can ascertain whether calculations of previous ASPs are correct. In addition, testimony regarding how defendants calculated the ASPs – including details concerning all of the sources of financial data that were mined – will assist plaintiffs with the task of determining ASPs for prior periods.

C. There Is Minimal Burden on Defendants

There is no question that calculating ASP is a complex process. It requires processing each invoice, each chargeback, each discount and all rebates. It may thus involve tens of thousand of transactions for a given drug. However, in responding to the new law, defendants have done these calculations. The burden of producing a witness to describe the results is minimal.

D. The Discovery Is Not Only Not "Unwarranted," It Is Fair

Plaintiffs sought by way of previous interrogatories to have defendants set forth the ASP for each drug. Defendants refused to do so instead asserting objections. *See* Exhibit B hereto by way of example.[7] Having not been able to obtain answers by way of interrogatory, plaintiffs are trying to calculate the ASPs from the incomplete data produced to date by defendant, but this has

[7] The nature of these objections is revealing of defendants' bad faith. For example, in refusing to answer, BMS asserts that the information is calling for the "compilation of information that is a public record." Defendants' AMPs reported to CMS are so confidential they are not shown to state Medicaid departments. AMPs are a close proxy to ASP and defendants' chargebacks, rebates and discounts are not only not public, they have been produced with "confidential" or "highly confidential" designations.

proven difficult, time consuming and may not be possible.[8] Thus, with the deadline for class certification fast approaching, the need to obtain ASP data is imperative and the witnesses sought are a vital first step in that process.

III. CONCLUSION

The information sought is narrowly focused, highly relevant and not burdensome. The motion should be denied.

DATED: June 24, 2004

By **/s/ Steve W. Berman**

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[8] BMS admits for example that its data is not complete and that rebate data is still coming. Schering has produced no data whatsoever as of yet.

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CERTIFICATE OF SERVICE

I hereby certify that I, Steve W. Berman, an attorney, caused a true and correct copy of the foregoing **PLAINTIFFS' OPPOSITION TO MOTION FOR PROTECTIVE ORDER** to be delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on June 24, 2004, a copy to Verilaw Technologies for Posting and notification to all parties

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